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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/184,043	11/02/98	HORNAUER	[redacted]

HM12/0828

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EXAMINER	
[redacted]	

ART UNIT	PAPER NUMBER
1641	18

DATE MAILED: 08/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/184,043	HORNAUER ET AL.	
	Examiner	Art Unit	
	Mary E. (Molly) Ceperley	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 July 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-21 and 52-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-21 and 52-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

1. The request filed on June 07, 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/184,043 is acceptable and a CPA has been established. An action on the CPA follows. Claims 14-21 and 52-29 are under consideration.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 14-21 and 52-59 are rejected under 35 USC 112, first and second paragraphs, as being based on a specification which contains an inadequate enabling written description of the invention and as being indefinite for the following reasons. *Note: the problems cited in paragraphs a)-q) are noted for the **first** time a given problem occurs but may also be present in and must be addressed for later appearing claims.*

a) In claim 14, the term "a solid phase reactant" fails to define the functionality of the "reactant" i.e. it cannot be determined what this moiety is required to react with. Page 4, lines 1-5 of the specification defines an "analyte-specific solid phase reactant", but the claim 14 term does not require this specificity.

b) In claim 14, it is not clear what is meant by the term "a modified solid phase reactant". What type of modification is intended? Page 8, second paragraph of the specification indicates that the intended "modification" somehow involves the use of a polyalkylene oxide but the term "modified solid phase reactant" does not require any specific modification. The language of the claim states that the "modified solid phase reactant" (i.e. previously somehow modified) is "coupled to a poly (C2-C3)-alkylene oxide". The language of the claim also states that the "solid phase reactant" (a separate entity from the "modified solid phase reactant") is immobilized "***using*** a modified solid phase reactant". This claim language is confusing as is the written description of page 8 of the specification wherein the "modified solid phase reactant" may or may not be "polyalkylene oxide-modified".

c) In claim 14, the nature, type and specificity of the "test reagent" are unspecified, thus rendering the claim indefinite.

d) Claim 14 is incomplete in not reciting (a) a positive method step wherein the analyte is bound to its specific binding partner, (b) a means by which the analyte is detected (e.g. the use of a detectable label), and (c) a step whereby the detection of a detectable signal is correlated with the presence/amount of analyte in the sample.

e) There is no antecedent basis in claim 14 for the use of the term "modified solid phase" of claim 15.

f) In the absence of functional or specific definitions of the terms "modified", "universal" and "reactant", it is unclear what is meant by the term "a modified universal

solid phase reactant" as recited in claim 15. ***Examples*** of "a universal modified solid phase reactant" are given at page 8 of the specification, but the specification provides no ***definitive definition*** of this term.

g) It is unclear what is meant by the term "a modified analyte-specific solid phase reactant" as recited in claim 16 and there is no adequate, specific definition in the specification of this term.

h) In claim 17, in the absence of the recitation of any specificity or function of the "biomolecule", the term "analyte-unspecific biomolecule" renders the claim indefinite.

i) In claims 17 and 18, the term "universal ***modified*** solid phase reactant" is inconsistent with the term "a partner of a high affinity binding pair" which is a single, ***unmodified*** moiety, for example, avidin.

j) In claim 18, it is unclear what the term "and polymeric conjugates thereof" modifies.

k) In claim 19, "haptens" and "sugars" are improperly defined as "partners of a high affinity binding pair" (claim 17).

l) In claim 20, there is no antecedent basis in claims 14 and 16 for the term "a conjugate with a partner of a high affinity binding pair". In addition, it is unclear what moiety is conjugated to the "***partner*** of a high affinity binding pair".

m) In claim 21, the terms "antibodies", "antigens", "nucleic acids", "nucleic acid analogues" and "lectins" are improper definitions of "analyte-specific modified solid

phase reactants". At the very least, these terms do not include any moieties which are "modified".

n) Claim 52 is indefinite and incomplete in not reciting the means by which the unspecific binding is reduced.

o) There is no antecedent basis in claim 14 for the term "the modified solid phase" of claim 53. Also, is the "modified universal solid phase reactant" the same moiety as "the modified solid phase"?

p) What constitutes a "***modified*** analyte-specific solid phase reactant" in claim 54?

q) In claims 21 and 59, the language should be changed to proper Markush format, i.e. "selected from the group ***consisting*** of".

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7.
~~6~~. Claims 14-21 and 52-59 are rejected under 35 U.S.C. 102(b)/(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over each of Sluka et al (U.S. 5,932,296), Herron et al (U.S. 5,677,196), Herron et al (U.S. 5,512,492), or Reichert et al (U.S. 5,832,165).

Each of the references describes the use of a PEG-modified solid phase reactant in a conventional immunoassay format as claimed in instant claim 14. These immunoassay methods anticipate the method of instant claim 14 which uses a PEG-modified solid phase reactant as the sole distinguishing, required component of the immunoassay format.

See:

a) Sluka et al: col. 1, lines 35-39; col. 4, lines 3-7, 14-63, in particular lines 38-42;

b) Herron et al ('196): col. 18, lines 21-29 and 39-44 ("biotin-PEG");

c) Herron et al ('492) : col. 2, line 50 - col. 3, line 9 ; col. 4, lines 2-5; claims 1, 17 (surface with "biotinylated polyethylene glycol") and 24;

d) Reichert et al: col. 13, line 66 – col. 14, line 2 ; col. 14, lines 11-24; col. 14, lines 58-60; col. 15, line 60 – col. 16, line 3 ("biotin-PEG" couple to surfaces).

The features of the dependent claims are either specifically described by the references (e.g. use of biotin or avidin/streptavidin as a "universal solid phase reactant: see streptavidin of Sluka et al, col. 4, line 40) or constitute obvious variations in parameters which are routinely modified in the art (e.g. use of conventional specific binding pairs of claim 59) and which have not been described as critical to the practice of the invention.

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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. (Molly) Ceperley whose telephone number is (703) 308-4239. The examiner can normally be reached from 8 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-7230.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

August 26, 2001

Mary E. Ceperley
Primary Examiner
Art Unit 1641